

Amendments to the Claims:

The following listing of claims replaces and supersedes all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original) A bacterial cell which is urease-deficient and which comprises a recombinant nucleic acid molecule encoding a fusion polypeptide comprising (a) at least one domain from a polypeptide, wherein said polypeptide domain is capable of eliciting an immune response in a mammal, and (b) a phagolysosomal escape domain.

2. (Original) The cell of claim 1 wherein at least one cellular urease subunit encoding nucleic acid sequence is inactivated.

3. (Original) The cell of claim 2 wherein at least the cellular urease C subunit-encoding sequence is inactivated.

4. (Original) The cell of claim 1, wherein said phagolysosomal escape domain is a *Listeria* phagolysosomal escape domain.

5. (Previously Presented) The cell of claim 1, wherein said phagolysosomal domain is encoded by a nucleic acid molecule selected from:

(a) a nucleotide sequence consisting of nucleotide 211-1722 as shown in SEQ ID No.1,

(b) a nucleotide sequence which encodes for the same amino acid sequence as the sequence from (a), and

(c) a nucleotide sequence hybridizing under stringent conditions with the sequence from (a) or (b), wherein said stringent conditions correspond to a condition in which a positive hybridization signal can be observed after washing for one hour with at least 0.2X SSC and 0.1 % SDS at a temperature of at least 55°C.

6. (Original) The cell of claim 1, wherein the domain capable of eliciting an immune response is a peptide or polypeptide capable of eliciting MHC class I-restricted CD8 T cell responses.

7. (Original) The cell of claim 1 wherein the domain capable of eliciting an immune response is from a Mycobacterium polypeptide.

8. (Original) The cell of claim 7, wherein the domain capable of eliciting an immune response is selected from the Mycobacterium antigens Ag85B (M. tuberculosis), Ag85B (M. bovis), Ag85A (M. tuberculosis) and ESAT-6 (M. tuberculosis) or an immunogenic fragment thereof.

9. (Original) The cell of claim 8, wherein the domain capable of eliciting an immune response is the antigen Ag85B or an immunogenic fragment thereof.

10. (Original) The cell of claim 1, wherein the fusion polypeptide is preceded by a signal peptide sequence.

11. (Original) The cell of claim 1, wherein a peptide linker is located between the immune response eliciting domain and the phagolysosomal domain.

12. (Original) The cell of claim 1, wherein said nucleic acid molecule is operatively linked with an expression control sequence.

13. (Original) The cell of claim 12, wherein said expression control sequence is active in said cell.

14. (Original) The cell of claim 1 wherein said nucleic acid molecule is located on a vector.

15. (Original) The cell of claim 1 which is a Mycobacterium cell.

16. (Original) The cell of claim 16 which is a Mycobacterium bovis cell.

17. (Original) A bacterial cell which is urease-deficient and which comprises at least one recombinant nucleic acid molecule encoding a phagolysosomal escape peptide or polypeptide.

18. (Previously Presented) The cell of claim 17, which further comprises at least one second recombinant nucleic acid molecule encoding a peptide or polypeptide capable of eliciting an immune response in a mammal.

19. (Original) The cell of claim 18 which is a *Mycobacterium* cell.

20. (Original) The cell of claim 19 which is a *Mycobacterium bovis* cell.

21. (Previously Presented) The cell of claim 1, wherein the domain or peptide or polypeptide capable of eliciting an immune response is selected from autoantigens, tumor antigens, virus antigens, parasite antigens, bacterial antigens and immunogenic fragments thereof.

22. (Previously Presented) The cell of claim 1, which is capable of expressing said at least one recombinant nucleic acid molecule.

23. (Original) The cell of claim 22, which is capable of secreting a polypeptide encoded by said at least one nucleic acid molecule.

24. (Previously Presented) The cell of claim 15, which has an intracellular persistence in infected macrophages which is equal or less than the intracellular persistence of a native *Mycobacterium tuberculosis* cell.

25. (Previously Presented) A pharmaceutical composition comprising as an active agent a cell of claim 1, optionally together with pharmaceutically acceptable diluents, carriers and adjuvants.

26. (Original) The composition of claim 25, which is a living vaccine suitable for administration to a mucosal surface or via the parenteral route.

27. (Previously Presented) A method for the preparation of a living vaccine comprising formulating a cell of claim 1 in a pharmaceutically effective amount with pharmaceutically acceptable diluents, carriers and adjuvants.

28. (Original) A method for preparing a recombinant bacterial cell of claim 1 comprising the steps:

- (i) providing a urease-deficient bacterial cell;
- (ii) inserting a recombinant nucleic acid molecule into said bacterial cell, said nucleic acid molecule encoding a fusion polypeptide comprising (a) at least one domain from a polypeptide, wherein said domain is capable of eliciting an immune response in a mammal, and (b) a phagolysosomal escape domain, and
- (iii) cultivating the cell obtained according to (ii) under suitable conditions.

29. (Original) The method of claim 28, wherein said cell is a *M. bovis* cell.

30. (Original) A method for preparing a recombinant bacterial cell of claim 17 comprising the steps:

- (i) providing a urease-deficient bacterial cell;
- (ii) inserting a recombinant nucleic acid molecule into said bacterial cell, said nucleic acid molecule encoding a phagolysosomal escape peptide or polypeptide and
- (iii) cultivating the cell obtained according to (ii) under suitable conditions.

31. (Previously Presented) The method of claim 30 further comprising inserting at least one second recombinant nucleic acid molecule into the bacterial cell, said second recombinant nucleic acid molecule encoding a peptide or polypeptide capable of eliciting an immune response in a mammal.

32. (Previously Presented) The method of claim 28, wherein the domain or peptide or polypeptide capable of eliciting an immune response is selected from autoantigens, tumor antigens, virus antigens, parasite antigens, bacterial antigens and immunogenic fragments thereof.

33-38. (Canceled)

39. (Currently Amended) A method of treating a mammal having ~~a disease state~~ tuberculosis, comprising administering to the mammal a bacterial cell according to claim 1 which comprises a recombinant nucleic acid molecule encoding a fusion polypeptide that elicits an immune response to ~~said disease state~~ tuberculosis, in a

pharmaceutically effective amount, wherein said polypeptide domain capable of eliciting an immune response to ~~said disease state~~ tuberculosis is selected from the group consisting of autoantigens, tumor antigens, virus antigens, parasite antigens, bacterial antigens and immunogenic fragments thereof that elicit an immune response to ~~said disease~~ tuberculosis.

40. (Currently Amended) The method of claim 39, ~~wherein the disease state is tuberculosis~~, wherein the polypeptide domain capable of eliciting an immune response to tuberculosis is selected from the group consisting of Mycobacterium antigens Ag85B (M. tuberculosis), Ag85B (M. bovis), Ag85A (M. tuberculosis), and ESAT-6 (M. tuberculosis) or an immunogenic fragment thereof that elicits an immune response to tuberculosis.

41. (Currently Amended) The method of claim ~~[[39]]~~ 48, wherein the mammal is immunodeficient.

42. (Previously Presented) The method of claim 41, wherein the disease state is a HIV infection, wherein the domain capable of eliciting an immune response to said HIV infection is selected from the group consisting of a HIV antigen, p17, p24, RT, and Env.

43. (Currently Amended) The method of claim ~~[[39]]~~ 48, wherein the mammal has a tumor and the administration of said bacterial cell treats the tumor, wherein the

domain capable of eliciting an immune response is a tumor antigen that elicits an immune response to said tumor.

44. (Currently Amended) The method of claim ~~[[39]]~~ 48, wherein the disease state is superficial bladder cancer, wherein the domain capable of eliciting an immune response is a tumor antigen that elicits an immune response to said superficial bladder cancer.

45. (Currently Amended) The method of claim ~~[[39]]~~ 48, wherein the mammal is an animal.

46. (Currently Amended) The method of claim ~~[[39]]~~ 48, wherein the mammal is a human.

47. (Currently Amended) The method of claim ~~[[39]]~~ 48, wherein the tumor antigen is selected from the group consisting of p53 tumor suppressor gene product that elicits an immune response to said tumor, a melanocyte differentiation antigen that elicits an immune response to said tumor, Melan- A/MART-1 that elicits an immune response to said tumor, and gp100 that elicits an immune response to said tumor.

48. (New) A method of eliciting an immune response to a disease state which is now or later may be in a mammal, comprising administering to said mammal a bacterial cell according to claim 1 which comprises a recombinant nucleic acid molecule

encoding a fusion polypeptide that elicits an immune response to said disease state, in a pharmaceutically effective amount, wherein said polypeptide domain capable of eliciting an immune response to said disease state is selected from the group consisting of autoantigens, tumor antigens, virus antigens, parasite antigens, bacterial antigens and immunogenic fragments thereof that elicit an immune response to said disease.